October 27, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on docket 99-1878

To Whom It May Concern:

Although these comments are later than the specified deadline, nonetheless, I feel compelled to write them. In your original guidance for performing HCV lookback, you allowed lookback to terminate on January 1, 1988. In the guidance published in June of this year, the FDA now recommends that lookback go on indefinitely. I work in a very large organization in which much time and money is already spent on lookback efforts. To-date, the HCV lookback that we have performed has yielded little valuable information. Most of the patients identified are either deceased or already well aware of their HCV infection. Resources that could be spent on current patient care issues are being diverted into this mandatory lookback effort with little value-added for any patient. Furthermore, prior to the 1970s different organizations had different record-retention time frames, thus making the lookback time frame different for each organization. From my perspective as a quality systems manager, it would be much better if a designated cut-off were specified by the FDA, such as January 1, 1988 or January 1, 1980. In that way, the data gathered will be standardized, meaningful, and consistent for regulatory evaluation without undue expense and without compromising medical care for any past, current, or future patient. Please take my comments into consideration when finalizing the guidance document on Current Good Manufacturing Practice for Blood and Blood Components. Thank you.

Sincerely,

Tania L. Motschman

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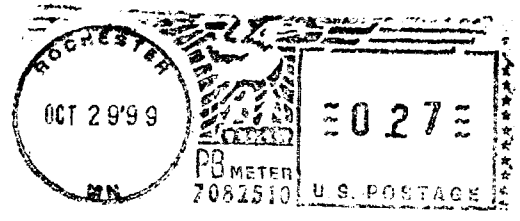

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